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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,890	01/09/2002	Roger Rogalski	521.515	1131
21707	7590	08/17/2004	EXAMINER	
IAN F. BURNS & ASSOCIATES 1575 DELUCCHI LANE, SUITE 222 RENO, NV 89502			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/045,890	Applicant(s) ROGALSKI <span style="float: right;">CN</span>	
	Examiner DAVID J ISABELLA	Art Unit 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 17, 18, 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16, 19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Status of the Claims***

Applicant's response filed on 5/10/2004 did not include any amendments to the claims, therefor claims 1-11,17,18,20,23-25 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species and claims 12-16,19,21,22 are pending for action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 12,13,15-16,21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Walder-Utz et al (5779720) or Archibald (4267842).**

Walder-Utz et al discloses a graft device comprising an interior tissue surface (16) and an exterior tissue surface (12). The device includes an attachment structure (17). The device contains a central portion ( that portion of the device forming the "c-shaped" sleeve terminating at the attachment structure (17); and fingers (10) are integral with the central portion of the sleeve. Likewise, Archibald discloses a graft device comprising a sleeve having a C-shaped cross section defining a cavity. The central portion of the sleeve contains at least one finger integrally attached thereto.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Archibald or Walder-Utz et al as applied to claim 12 above, and further in view of Shichman et al (5439479).**

While Walder-Utz et al is not specific to the material composition of the surgical clip, Shichman et al teaches that bioabsorbable material may be used to make surgical clips. It would have been obvious to one with ordinary skill in the art to fabricate the surgical clip of Walder-Utz et al from a bioabsorbable material to allow for the slow invasion of natural tissue growth into the surgical site in view of the teachings of Shichman et al.

***Claim Rejections - 35 USC § 103***

**Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walder-Utz et al or Archibald as applied to claim 12 above, and further in view of de Medinaceli.**

The use of visual markings or indicators on graft devices to allow for more accurate reference for the surgeon is taught by de Medinaceli. To provide the graft

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device of either of Walder-Utz et al or Archibald with visual markings or indicators to facilitate proper placement of the device in vivo would have been obvious to one with ordinary skill in the art from the teachings of de Medinaceli.

### ***Response to Arguments***

Applicant's arguments filed 5/10/2004 have been fully considered but they are not persuasive. With respect to the outstanding rejection under 35USC102 by Walder-Utz et al or Archibald, applicant's argues that the devices are not for assisting in grafting by providing a protective surface to protect the tissue portion of the graft during surgical procedure. The preamble of the claim is directed to a graft device and the body of the claim defines the device as having an interior tissue facing surface and an exterior protective surface configured to serve as a barrier for the tissue portion of the graft. The functional language of the claim is directed to the subject of applicant's arguments. Structurally, Walder-Utz et al and Archibald discloses, respectively, a graft device comprising an interior tissue facing surface and an exterior surface. Each device, respectively further includes an attachment structure that is configured to attach the graft device to the tissue portion of the graft. While there is no specific teaching that either device has the specific function for protecting the tissue portion of the tissue from damage by surgical instruments during surgical operation, the outer surface of each device would inherently provide the function as broadly claimed. Each device, by the very nature of the materials and configuration would, inherently, act as a protective sleeve, or jacket about that portion of the tissue to which the device has been applied.

Applicant's claims are so broadly worded ( ie no structural features, dimensions, configuration) so as not to preclude a device as a surgical clip or an arterial sleeve, each of which provide the structure as claimed; and the structure is inherently capable of performing the function of protecting the tissue portion of the tissue to which it is attached.

With respect to claim 19, the use of a bioabsorbable material in the manufacture of clips or sleeves is well known in the art as an alternative to devices which are designed for permanent placement in the body. If there is a concern about leaving a device implanted over an indefinite amount of time, the use of absorbable material is well known in the art as taught by Shichman et al. Bioabsorbable devices enjoy known advantages over the permanent-type devices, these advantages include reduced scar tissue formations, reduced inflammations and infections and theses devices favor new tissue formation and regeneration at the injury site. For all the well known reasons, it would have been obvious to one with ordinary skill in the art to fabricate either devices, Walder-Utz et al or Archibald from a material that is absorbed to minimize the chances of long term failure of the permanent device due to scar tissue formation, inflammation and/or rejection.

With respect to claim 14, applicant argues that the claim is dependent on claim 12 and relies on the argument that the primary reference fails to disclose or teach a device with an exterior protective surface. Examiner maintains that Medinaceli teaches the concept for providing inscribed lines or markings to allow for proper placement of the device in vivo is well known. To provide either device of Walder Utz et al or

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Archibald with visual indicators to aid the surgeon in proper placement of the device in vivo would have been obvious to one with ordinary skill in the art at the time of the invention. Examiner maintains that the guide mark need not be used for visual reference specifically to assist the insertion of an interference screw in a bone tunnel, but rather the guide mark must be capable of assisting the surgeon in the placement of the device in vivo and may include the specific function related to the insertion of an interference screw. Other than the broad language of "the guide mark being configured to provide visual reference to assist insertion of an interference screw" the claim lacks specifics directed to the actual features that allow for the particular device to provide for the function of assisting the insertion of the screw. Therefore a device with a visual marker would certainly be capable of assisting the insertion of a screw.

Examiner maintains that there is sufficient motivations supplied from each of Shichman et al and Medinaceli, respectively, to modify the devices of the primary references. In each instance, the advantages offered by the secondary references are well known to one with ordinary skill in the art and these advantages would allow the surgeon and patient to enjoy a device that can be more easily placed in vivo with reduced open air time resulting in a reduced likelihood for failure.

### **Citation of pertinent prior art**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ryan et al                      5984963

Demopoulos et al        6080192

### ***Conclusion***

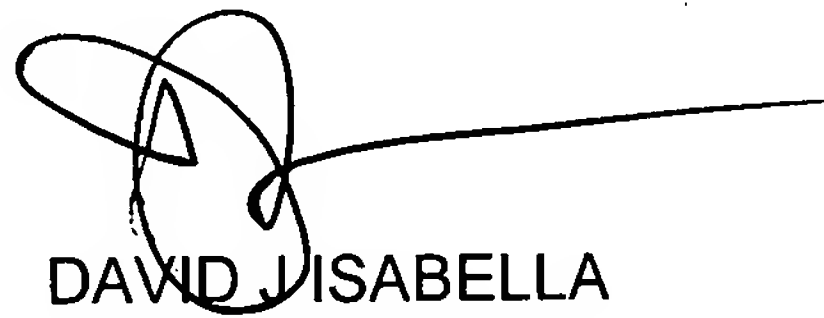
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
AUGUST 11, 2004